

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 17 requires the pigments to be absorbed within a time period of less than twenty minutes. This limitation is only disclosed when using saline; not a salt-based granular paste in combination with saline.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5, 9, 14-16, 18, 21-24, 28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malodobry (US 2004/0111107) in view of Bogart et al. (US 5,271,943).

Regarding claims 1, 5 and 9, Malodobry discloses a method for removing pigments from a pigmented section of skin, comprising: a) puncturing the skin at said pigmented section with a skin-puncturing device provided with at least one solid needle, thereby liberating the pigments and cellular fluids from cells containing said pigments (paragraphs 0043-0048). Malodobry fails to explicitly state that pigments are liberated from within cells in regards when using his method. However, Malodobry clearly discloses that the pigments reside within intact cells (paragraph 0035) and goes on to give an example of how the diathermy technique is used to liberate pigments from these intact cells (paragraph 0035). Therefore, it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to have used the Malodobry puncturing step to liberate pigments from within cells as claimed since Malodobry discloses that pigments reside within cells. Malodobry fails to disclose b) bandaging said punctured skin with a pad adapted to absorb said pigments and said cellular fluids, said pad containing one or more materials capable of accelerating a process of migration of said pigments toward an outer layer of the skin, wherein said one or more materials is a salt-based granular paste. Malodobry does disclose using irritants such as sodium chloride to increase exudate and thereby increase the amount of pigments migrating towards the outer layer (this is clearly the intent of using irritants as disclosed in paragraphs 0050-0052; Examiner notes that the use of irritants is disclosed immediately after Malodobry discloses an intent to use wound exudate to carry pigments to the skin surface; see paragraph 0049). Bogart et al. disclose bandaging a wound with a pad (col. 9, lines 31-35; col. 3, lines 49-54) containing a sodium chloride

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based granular (col. 4, lines 42-46) paste (a granular gel can be considered as a paste; Applicant has provided experimental data which disclosed the paste as KY gel and salt) to accelerate a process of skin exudate and bacteria migration to an outer layer of skin (col. 4, lines 60-63; col. 9, lines 44-60). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention and in view of Bogart et al. to have used a pad and paste as claimed for a number of reasons. For example, Malodobry suggests using a sodium chloride irritant but does not give a specific method for applying it. The device and method of Bogart et al. would provide one of ordinary skill in the art with a specific device and method for implementing Malodobry's suggestion of using a sodium chloride irritant to increase wound exudate or drainage. One of ordinary skill in the art would also recognize that the device and method of Bogart et al. would especially enable the exudate to carry the pigments as intended by Malodobry because Bogart et al. teach that their method would cause exudate to sweep bacteria to the outer layer and bacteria can be as large or larger than the pigment agglomerates. One of ordinary skill in the art would at least be motivated to apply the method of Bogart et al. to heal the wound of Malodobry after the pigments are substantially removed. The step(s) provided by Bogart et al. could still be considered as part of the overall method of pigment removal. Finally, one of ordinary skill in the art would be motivated to use the Bogart et al. formulation because Malodobry suggest using NaCl as a dispersion – where a dispersion is differentiated from a solution (paragraph 0052). Bogart et al. disclose a dispersion of NaCl in a gel which has an unusually high yield point and

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viscosity, which improves its adherence to a wound (col. 2, lines 47-65 and col. 3, lines 10-18).

Regarding claims 2 and 15, Bogart et al. further teach applying one or more antiseptic materials to the punctured skin via the paste (col. 6, lines 27-28 and elsewhere).

Regarding claim 3, the paste of Bogart et al., containing the antiseptic materials, can be applied with a pad as explained above.

Regarding claim 4, the skin-puncturing device of Malodobry is a tattooing device (paragraph 0046).

Regarding claims 14 and 31, Malodobry discloses injecting aqueous irritant into the pigmented section as claimed (paragraphs 0050 and 0052). It would have been obvious to one of ordinary skill in the art to have maintained this step when modifying with Bogart et al. because one of ordinary skill in the art would recognize that this step could further help the process of pigment migration in addition to the modification described above.

Regarding claim 16, Bogart et al. teach impregnating the pad with the gel (col. 3, lines 49-54) as well as providing antibiotics within the gel as described above.

Regarding claim 18, Malodobry discloses that the needle is hollow (paragraph 0043).

Regarding claim 21, it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to have not provided tattooing ink with the tattooing

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device in the above method because the method is intended to remove ink already present in the skin.

Regarding claim 22, it would have been obvious to one of ordinary skill to remove the pad before damaging the skin as a matter of common sense.

Regarding claim 23, Bogart et al. teach that the pad should be designed to hold exudate away from the wound (col. 9, lines 36-38). Therefore, it would have been obvious to one of ordinary skill in the art to have removed the pad prior to complete saturation in order to prevent excess exudate from leaking out of the pad and on or around the wound. Furthermore, it would have been obvious to one of ordinary skill to remove the pad prior to saturation in order to prevent the pad from leaking fluid onto a patient.

Regarding claim 24, Bogart et al. teach securing an absorbent dressing or pad (col. 9, lines 31-34; col. 10, lines 46-49). Examiner takes official notice that it is old and well-known in the art that absorbent pads are typically applied by wrapping or securing an absorbent pad to a wound with gauze or medical tape. Therefore, it would have been obvious to one of ordinary skill in the art to have secured an absorbent dressing or pad to the wound using by wrapping or covering the pad with gauze or medical tape. The above well-known in the art statement is taken to be admitted prior art because Applicant did not traverse Examiner's assertion (MPEP 2144.03).

Regarding claim 27, Bogart et al. teach removing the pad after draining a sufficient amount of exudate and then applying a second pad to promote healing as explained above. Bogart et al. also teach applying antibiotics as explained above. It

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would therefore have been obvious to one of ordinary skill in the art at the time of Applicant's invention to have provided antibiotics on the second pad because they would promote healing by reducing the chance of infection.

Regarding claim 28, Bogart et al. disclose bandaging the wound with a pad impregnated with the paste (col. 3, lines 43-53; col. 13, lines 4-6).

4. Claims 6, 7, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malodobry (US 2004/0111107) in view of Bogart et al. (US 5,271,943) and further in view of Garitano et al. (US 2004/0158196).

Regarding claims 6, 7, 19 and 20, Malodobry in view of Bogart et al. disclose the invention as described above. They do not disclose performing the suction of the pigments from said punctured skin with the suction means prior to the bandaging of the punctured skin and during the puncturing of said skin. Garitano teaches the suction of a solution provided for the removal of tattoos (paragraph 0023). Performing this step during the puncturing step would have been obvious to a person having ordinary skill in the art because prior to this step, there is no fluid to be suctioned. Also, performing this step prior to bandaging would have been obvious because after bandaging, the suction step would not be easily performed. Furthermore, the Examiner notes that no specific advantage was provided for the ordering of these steps so it is considered within the purview of one having ordinary skill in the art to rearrange the order of steps (see MPEP 2144.04 IV C). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the Malodobry removal steps to include Garitano's suction step. Such a modification would draw fluid from the tattoo to

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further aid in the removal of the pigments. Since Malodobry discloses that the needles used to perform the puncturing are capable of suctioning liquids (paragraph 0043), it would have been obvious to modify the puncturing device to be capable of suctioning in order to apply the Garitano teaching. Malodobry further discloses that other prior art methods of pigment removal should also be used simultaneously (paragraph 0053).

5. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malodobry (US 2004/0111107) in view of Bogart et al. (US 5,271,943) and further in view of Dosch et al. (US 7,012,096 B2).

Regarding claim 17, Bogart et al. disclose using any gelling agent for their invention. Dosch et al. disclose a gelling agent composition suitable for pain mediation of wounds (claim 9) which can be applied for 20 minutes (col. 12, lines 23-25) and other short periods. Therefore, it would have been obvious to one of ordinary skill in the art to have used the gelling agent composition of Dosch et al. with the paste of Bogart et al. in order to sooth pain and to have applied the paste for 20 minutes or less.

Response to Arguments

6. Applicant's arguments, including the Affidavit, filed August 8th 2011, have been considered but are not persuasive. Applicant has argued that Malodobry intends to slow the healing process down; not accelerate it – which is the intent of Bogart et al. Therefore, one of ordinary skill in the art would not consider Bogart et al. when attempting to modify or improve the method of Malodobry. Examiner respectfully disagrees. Malodobry only considers slowing down the healing process when using fillers which do not have an irritant effect (paragraph 0050). Slowing of the healing

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process is only mentioned once in direct regard to the use of non-irritant fillers. One of ordinary skill in the art would understand from paragraph 0050 that when a filler does not have an irritant effect, the only way for it to cause excess exudate production would be to delay healing of the wound. Applicant has argued that one of ordinary skill in the art would consider that Malodobry teaches exactly how salt should be applied to the wound and would not look for alternate means for its application. Examiner does not see where in Malodobry it is clearly disclosed how salt should be applied to the wound. Malodobry suggests applying the irritants in a dispersion (paragraph 0052). This is a general statement, meant for any of the irritants disclosed; salt being one. It is not fully disclosed how salt would be formulated as a dispersion. Note that dispersion has been differentiated from solution (paragraph 0052). In this sense, "dispersion" is not referring to a solution of dissolved salt in some liquid. Bogart et al., if nothing else, teach how to formulate salt as a dispersion in a gel matrix so that it can be applied to a wound. They further teach that this formulation prevents the salt from running out of the wound and allows it to enter the crevices of a wound for better tissue contact (col. 2, lines 47-65 and col. 3, lines 10-18 end elsewhere). In fact, this is one of the most important inventive concepts in Bogart et al. The basic teaching of Bogart et al. is that their range of salt concentrations, when mixed with a gel (any gel - col. 6, lines 36-37), create a substance that has an unusually high yield point and viscosity and will not ooze out of a wound (col. 2, lines 47-65 and col. 3, lines 10-18). Nowhere do they mention eliminating the irritant effect of salt. If this is implied in the reference then one would have to believe that any gel can eliminate the irritant effect of salt. Therefore, one of

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ordinary skill in the art wishing to formulate salt as a dispersion and still maintain its irritant effect would look to any area of the prior art that teaches this. Furthermore, Malodobry discloses that the natural healing process is used to eject the pigments (paragraphs 0041, 0045, 0048 and 0049); therefore not discouraging and possibly motivating one of ordinary skill in the art to look into areas where wound healing is promoted.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Thomas McEvoy** whose telephone number is **(571) 270-5034**. The examiner can normally be reached on Monday-Friday, 9:00 am – 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Tom Hughes at 571-272-4357***. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

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/T. M./

Examiner, Art Unit 3731

/S. Thomas Hughes/

Supervisory Patent Examiner, Art Unit 3731